

510(K) Summary of Safety and Effectiveness

The Wako Autokit C3 test is an in vitro assay for the quantitative determination of C3 in serum.

Summary:

The Complement System is a plasma-based protein cascade, which functions as a highly regulated and effective immune barrier. The term "complement" dates from a turn of the century observation that certain heat labile components in human and animal sera enhanced or "complemented" its antibacterial activity. With the advent of advanced protein purification techniques in the 1960's, the Complement System was shown to be a true cascade of proteins comprised of more than thirty membrane bound and plasma components that work in concert to promote immune functions. The Complement System is comprised of four main protein cascades called the Classical, Alternative, Terminal, and the newly discovered Mannan Binding Lectin pathways. Complement has three primary functions including the enhancement of phagocytosis through opsonization and solubilization of immune complexes, lysis of target cells and microorganisms, and the release of anaphylatoxins.

C3 is central to all complement pathways and the most abundant circulating complement protein. Measurement of C3 (like C4 and C50) is an important index for the diagnosis of immune disease like lupus nephritis, allergies and inflammation. Because C3 is produced primarily in liver, C3 is also important in monitoring fulminant liver disease.^{1,2} Autokit C3 is a highly specific immunoturbidimetric assay for quantitative measurement of C3 in human specimens.

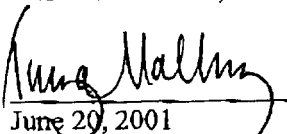
Principle:

When a sample is mixed with reagents, C3 in the sample forms antigen-antibody complex with anti-C3 antibody (goat). The intensity of turbidity caused by the formation of the complexes is proportional to the amount of C3. By measuring the absorbance of the reaction mixture, the C3 amount in the sample is determined.

Precision studies indicate acceptable values can be obtained on a day to day basis. The minimum detectable level of this method is estimated to be 1.7 mg/dL. In comparison studies against the predicate, a correlation coefficient of 0.9004 and a regression equation of $y = 0.90x + 20.2$ was obtained.

References:

1. Burtis, C.A. and Ashwood, E.R., Ed.: Tietz Textbook of Clinical Chemistry, 2nd Ed., Saunders, Philadelphia, 1994.
2. Lothar Thomas, M.D., Ed.: Clinical Laboratory Diagnostics.



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JUN 25 2001

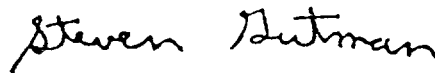
A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in dark ink that reads "Steven Gutman". The signature is written in a cursive, slightly slanted style.

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

Page 1 of 1

510(k) Number: K010326

Device Name: Wako Autokit C3 and Immunoassay Calibrator

Indications for Use:

This reagent test system is used to measure complement component C3 in serum. Complement is a group of serum proteins which destroy infectious agents. Measurement of these proteins aid in the diagnosis of immunologic disorders, especially those associated with deficiencies of complement components.

In comparison studies against a commercially available nephelometric assay, a correlation coefficient of 0.9004 and a regression equation of $y = 0.90x + 20.2$ was obtained.



(Division Sign-Off)

Division of Clinical Laboratory Devices

510(k) Number K010326

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)